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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/215,569

Applicant(s)

Bier et al.

Examiner

David Romeo

Group Art Unit

1647



☒ Responsive to communication(s) filed on 22 Dec 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-26 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-26 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, drawn to a polynucleotide comprising SEQ ID NO: 1, classified in
5 class 536, subclass 23.1.
 - II. Claims 3, 4, drawn to a peptide comprising SEQ ID NO: 2, classified in class 530,
subclass 300.
 - III. Claims 5, 6, drawn to a mAb against the peptide of II, classified in class 530,
subclass 388.23.
 - 10 IV. Claims 7, 8, drawn to a polynucleotide comprising SEQ ID NO: 3, classified in
class 536, subclass 23.1.
 - V. Claims 9, 10, drawn to a peptide encoded by SEQ ID NO: 3, classified in
class 530, subclass 350.
 - VI. Claims 11, 12, drawn to a polynucleotide comprising SEQ ID NO: 5, classified in
15 class 536, subclass 23.51.
 - VII. Claim 13, drawn to a peptide, classified in class 530, subclass 350.
 - VIII. Claims 14, 15, drawn to mAbs, classified in class 530, subclass 388.23.
 - IX. Claims 16, 17, drawn to a polynucleotide comprising SEQ ID NO: 7, classified in
class 536, subclass 23.1.

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X. Claims 18, 19, drawn to a peptide encoded by SEQ ID NO: 7, classified in class 530, subclass 350.

XI. Claims 20, 21, drawn to mAbs against a peptide encoded by SEQ ID NO: 7, classified in class 530, subclass 388.23.

5 XII. Claim 22, drawn to a treatment method comprising administering the peptide of claim 3, classified in class 514, subclass 12.

XIII. Claim 23, drawn to a treatment method comprising administering the peptide of claim 9, classified in class 514, subclass 12.

10 XIV. Claim 24, drawn to a treatment method comprising administering the peptide of claim 12, classified in class 514, subclass 12.

XV. Claim 25, drawn to a treatment method comprising administering the peptide of claim 18, classified in class 514, subclass 12.

XVI. Claim 26, drawn to a measuring or testing process, classified in class 435, subclass 4.

15 2. The inventions are distinct, each from the other because of the following reasons:

a. The following pairwise combinations of products are independent and distinct, wherein neither member of a pair is required for the production or use of the other, and wherein each of the pair can be manufactured independently of the other and/or used for independent and distinct purposes: I and each of IV, VI, IX; IV and each of VI, IX; VI and each of IX; II and

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each of V, VII, X; V and each of VII, X; VII and each of X; III and each of VIII, XI; VIII and each of XI;

b. The following pairwise combinations of products and methods are independent and distinct, wherein the respective products may neither be produced by, nor used in the respective
5 methods: I and each of XII-XVI; III and each of XII-XVI; VIII and each of XII-XVI; XI and each of XII-XVI;

c. The following pairwise combinations of methods are independent and distinct, wherein each member of a pair performs different functions and/or uses different starting materials and/or process steps and/or with different outcomes: XII and each of XIII-XVI; XIII and each of
10 XIV-XVI; XVI and each of XV-XVI; XV and each of XVI;

d. Each of the polynucleotides of Inventions I, IV, VI, IX are related to the polypeptides of Invention II, V, VII, X, respectively, by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the
15 specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic polypeptide synthesis or purification from the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as a nucleic acid hybridization assay.

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e. Each of the polypeptides of inventions II, V, VII, X are related to the antibody of Inventions III, VIII, XI, respectively, by virtue of being the cognate antigen, necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists.

f. Each of the polynucleotides of invention I, IV, VI, IX and the antibody of Invention III, VIII, XI, respectively, are related by virtue of the polypeptide that is encoded by the polynucleotide and necessary for the production of the antibody. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

g. Each of Inventions II, V, VII, X and each of XII-XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Inventions II, V, VII, X can be used in an immunization protocol for the production of antibodies.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 6:45 A.M. TO 3:15 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

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OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING
SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

MARCH 20, 2001